Thank you Mr. Chairman and members of the Task Force for the opportunity to testify today.

I am Joel Miller, Acting Director of the Policy Research Institute at the National Alliance for the Mentally Ill, known as NAMI. NAMI is a grassroots advocacy organization representing over hundreds of thousands of people with serious mental illnesses. We have 50 state NAMI organizations and over 1000 community affiliates across the country.

The Policy Research Institute recently convened a task force to develop recommendations on importation.

I would like to preface our task force recommendations on importation by making the following points.

Significant progress has been made in discovering new and effective medications for the treatment of patients with serious mental illness.

These advancements have enabled persons with serious mental illness to improve significantly and to remain in their communties and with their families, leading productive, rewarding, and dignified lives.

Having said that, we are very concerned that unlike many medications that treat other illnesses, medications that treat serious mental illness cannot used be interchangeably. Each psychiatric medication has a very different mechanism of action and the brain is such a complex organ and mental

illnesses are so complex, medications affect each person's brain in a very different way.

So we are extremely concerned that if medications are modified accidently or inappropriately in any way (or people with serious mental illness receive mislabeled medications), the side effects can be extremely serious and worsen the patient's condition.

In addition to the specific issues pertaining to psychiatric medications, the following observations guided the task force's deliberations:

First, that importation of medications by wholesalers as envisioned in various congressional proposals is very different from Americans going to a licensed pharmacist in Canada. It is our understanding that these wholesalers would not have to meet either Canadian or U.S. standards or licensure requirements. Further, nothing would require these wholesalers to pass on cost savings to U.S. consumers.

Second, the issue is not safety standards across the U.S.-Canadian border, but lack of standards for products coming into Canada from other countries -- where there may not be product of origin labeling requirements.

Third, over the next five years, several atypical antipsychotic medications will become available in long lasting injectible forms. These new technologies require special handling and storage in accordance to standards set forth by the FDA and the manufacturer. The FDA must be given the

legal and regulatory authority to ensure that these products meet these safety standards before reaching U.S. consumers.

Based on these considerations, NAMI's policy on imporatation is:

1. Safety and efficacy must remain the most important considerations in prescription medications used by consumers with serious mental illnesses.

2. Due to safety and quality considerations raised by the FDA, at this time, we support the provision in the Medicare Drug Benefit law whereby only medications from Canada should be reimported and medications must be certified for their safety by HHS.

3. Although NAMI supports this safety provision in the Medicare law, we recognize that individuals, especially in the border states to Canada, will seek more affordable medications by traveling across the border to purchase them. Currently, individuals seeking less expensive medication who cross the border and return with reasonable quantities of their prescription drugs should not be prosecuted by the FDA.

4. NAMI believes that states should not be sanctioned for their actions to allow their employees to purchase medications from Canada as long as the those medications are certified by the HHS, as mandated in the Medicare Drug Benefit law.

5. NAMI has grave concerns about importation and reimportation of medications through Internet-based pharmacies. The importation and reimportation of medications through these operations compromises public health and safety.

6. NAMI supports the need for the FDA to study the safety issues surrounding the importation and reimportation of medications and report back to Congress in 2005 on a plan to certify the safety of medications that are imported and reimported from Canada.

NAMI will closely monitor the work of the FDA Task Force on Importation, and based on the FDA's recommendations, reexamine policy positions on importation and reimportation.

Thank you again for the opportunity to present NAMI's positions on the importation of prescription medications.